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71A

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

08/14/16

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/361,652

Applicant

C.S. Zuker et al.

Examiner
Michael Brannock, Ph.D.

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 4, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 8-18, 34, 35, and 61-63 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 8-18, 34, 35, and 61-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 15
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Status of Application: Claims and Amendments

1. Claims 1, 3-6, 8-18, 34, 35, and 61-63 are pending and are currently under examination.
2. Applicant is notified that the amendments put forth in Paper 14, 6/9/01, have been entered in full.

Maintained Objections:

3. The objection to the specification put forth in item 5 of Paper 8 is maintained until the required updates are made.

Maintained Rejections:

4. Claims 1, 3-6, 8-18, 34, 35, and 61-63 stand rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, as set forth item 9 of Paper 12 (1/3/01).

Applicant argues that the instant polynucleotides and polypeptides are expressed specifically in taste buds and encode a taste bud cell specific GPCR, and are thus useful for the identification of ligands that bind to the polypeptide, for screening for modulators of the polypeptide, and as specific markers for taste bud cells. This argument has been fully considered but not deemed persuasive. The above assertions are not in dispute. As set forth previously, these proposed uses do not constitute a specific or otherwise substantial utility.

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Applicant argues that experimental data has been provided demonstrating that the instant polypeptide is a functional GPCR. Again, this assertion is not in dispute, the issue remains that the specification has not sufficient guidance as to the particular properties of the polypeptide that enable the skilled artisan to use the polypeptides in a way that constitutes specific or otherwise substantial utility.

Applicant argues that the polynucleotides can be used in assays for modulators of taste transduction, such a use not being merely a starting point for further research and investigation. This argument has been fully considered but not deemed persuasive. As set forth previously, the proposed use of the polypeptide to screen for ligands of the polypeptide or for biologic effects of the polypeptide is not a substantial utility. A substantial utility is a practical use which amounts to more than a starting point for further research and investigation and does not require or constitute carrying out further research to identify or reasonably confirm what the practical use might ultimately be. The specification has not asserted that the claimed polypeptides are involved in any particular aspect of what is collectively known as the perception of taste. Thus, the skilled artisan would need to perform further research and investigation on the properties of the instant polypeptides to determine which, if any, aspect of taste perception is mediated by the instant polypeptides. No particular tastant molecules are asserted to stimulate the instant polypeptides. No particular molecules are asserted to bind to the polypeptides and mediate or modulate any aspect of taste perception. The specification has not put forth that the polypeptides

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are involved in taste perception in any particular way. Thus, the skilled artisan would not know how to use the claimed polynucleotides without first performing further research and investigation. Further, Applicant argues that the property of taste cell specific expression provides opportunities to use the polynucleotides in ways that have specific, substantial and credible utilities, such as taste cell specific markers and in the development of taste topographic maps which could elucidate relationships between taste sensory neurons and the brain. This argument has been fully considered but not deemed persuasive. As indicated, the use of a polypeptide/polynucleotide as a tissue specific marker, is not in and of itself, a specific or otherwise substantial utility. The property of taste cell specific expression is a general property of polynucleotides that are expressed in taste cells, of which many are known. The invitation to develop taste topographic maps is simply an invitation to the skilled artisan to study the properties of the claimed polynucleotides and to study the mechanisms in which the polynucleotides are involved. Such an invitation to perform research and investigation does not constitute a substantial utility.

5. Claims 1, 3-6, 8-18, 34, 35, and 61-63 also stand rejected under 35 U.S.C. § 112 first paragraph, as set forth in item 10 of Paper 12. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

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Applicant argues that no reasoning has been provided to explain why one of skill could not practice the claimed invention using the specification and standard techniques, e.g. to make expression vectors and to test for GPCR activity. This argument has been fully considered but not deemed persuasive because the specification has been examined with regard to enablement for specific and otherwise substantial uses. As indicated above, the specification fails to teach one skilled in the art how to *use* the claimed nucleic acids in a way that constitutes a patentable utility, without further research and investigation.

6. Claims 1, 3-6, 8-18, 34, 35, and 61-63 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth in item 11 of Paper 12. Applicant argues that the specification and claims set forth both functional and structural elements of the claimed genus of polynucleotides, e.g. the ability to hybridize to reference sequences. Such elements meeting the standards set forth in *University of California v. Eli Lilly*. This argument has been fully considered but not deemed persuasive. Contrary to Applicants' assertion, no particular functional limitations for the encoded polypeptides are required by the claims which might limit the genus to that which is adequately described. The function of binding an antibody (as is required by the claims) is simply a physical property of the polypeptide and need not have anything to do with function. Further, the recited "G-protein coupled receptor

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activity” is a broad conceptual function and does not constitute an actual particular function, thus, this limitation does not further limit the claims to that which is adequately described. The requirement that the polynucleotides hybridize under stringent conditions is a broad structural limitation that does not limit the claimed genus to a number of species that reasonably describes the essential elements of the genus such that one of skill in the art would recognize that Applicant was in possession of the genus, i.e. no particular structural features are required of the members of the genus and there are no functional elements that link the vast number of disparate members of this genus.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.


Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



August 11, 2001



YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600